

SEP 19 2001

K011241

## I. 510K SUMMARY

Submitted by: Neurosoft, Inc.  
45150 Business Court, Suite 100  
Sterling, VA 20166  
Phone: 703-904-9600  
Fax: 703-904-7870

Contact Person: Elvira Garcia; Quality Engineer  
Neurosoft, Inc.  
5700 Cromo Drive, Suite 100  
El Paso, TX 79912  
Phone: 915-845-5600 ext. 17  
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Egarcia@neuroscan.com

Date Prepared: June 25, 2001

Proprietary Name: Neurosoft, Inc.  
  
**Neurosoft Source®**

Common Name: Electroencephalograph (EEG) Software

Classification Name: Electroencephalograph (GWQ) Software

Predicate Device: Neurosoft Curry® (K001781)

Device Description: The Neurosoft Source® integrates multiple, complementary image modalities (EEG and/or MEG with MRI, fMRI, CT) in a single software package for electromagnetic source localization and visualization.

Intended Use: The Neurosoft Source® is intended for use by qualified/trained EEG technologist and/or physicians on both adult and pediatric subjects for the visualization and to help analysis of the electrical activity of the brain by fusing a variety of EEG and/or Magnetoencephalographic (MEG) data, with Magnetic Resonance (MRI) functional Magnetic Resonance (fMRI), Computer Tomography (CT).

Technological Characteristic: The Neurosoft Source® has similar technological characteristics and indications for use, and is therefore substantially equivalent to Neurosoft's Curry®.

Safety and Effectiveness Comparison to Predicate: The results of bench and user testing indicate that the software is safe and effective as the predicate software.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

SEP 19 2001

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Elvira Garcia  
Quality Engineer  
Neurosoft, Inc.  
5700 Cromo Drive, Suite 100  
El Paso, Texas 79912

Re: K011241

Trade/Device Name: Neurosoft SOURCE™ Software  
Regulation Number: 882.1400  
Regulation Name: Regulation Name: Electroencephalograph  
Regulatory Class: II  
Product Code: GWQ  
Dated: June 25, 2001  
Received: June 27, 2001

Dear Ms. Garcia:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative  
and Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

## II. Statement of Indication for Use

Applicant: Neurosoft, Inc.  
45150 Business Court, Suite 100  
Sterling, VA 20166  
Phone: 703-904-9600  
Fax: 703-904-7870

510(k) Number: K011241

Device Name: Neurosoft **SOURCE® Software**

Indication for Use: The Neurosoft Source® is intended for use by qualified/trained EEG technologist and/or physicians on both adult and pediatric subjects for the visualization and to help analyze the electrical activity of the brain by fusing a variety of EEG and/or Megnetoencephalographic (MEG) data, with Magnetic Resonance (MRI) functional Magnetic Resonance (fMRI), Computer Tomography (CT).



(Division Sign-Off)  
Division of General, Restorative  
and Neurological Devices

510(k) Number K011241